1722-CC00650

WIN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS, MISSOURI
22nd JUDICIAL CIRCUIT

TIMOTHY LAWSON;
HEATHER SENN, as NEXT FRIEND for **C.A.** ;
DONNAVIN NEGRON;
APRIL BURKS, as NEXT FRIEND for **E.J.** ;
VESHANDUS FLEMINGS, as NEXT FRIEND for **E.F.** ;
STEFANIE PARKER, as NEXT FRIEND for **A.P.G.** ;
ANTHONY KING;
WILFRED HOLLAND;
TERRELL MCGOWAN;
MICHAEL NOTE;
ERIC TAYLOR;
LATREND WOODLAND;
LAURENCE JORDAN;
ROBERT JONES;
LEON DAVIS-HUBERT;
JUSTIN LUONGO;
BRIAN JONES;
JAMES HATCHER;
BRYAN DRAHEIM;
JASON MOORMAN;
JONATHAN HADDIX;
BRIAN MATTINGLY;
JOVAN HOPINGS;
MICHAEL SMITH;
LAMEL DAVIS;
ARRON THOMAS;
TYSHON YOUNGE;
PAUL GILMORE;
KEVIN WOODS;
NICHOLAS ANDREWS;
BRENDAN MAKAREWICZ;
TIMOTHY BERNARD;
DUPREE HINDS;
ELIAS RAMIREZ;
ALEKSANDR GRESHZON;
JOSHUA NORCOTT;
ERIC HALL;
TYRON DUTTON;
ALEX HARLOW;
LEE SMITH;
DANIEL TURLEY;
DESMOND GUILLORY;
RONALD RIVERS;
JASON STENSON;
WILLIAM MORRIS;

Case No.: _____

JURY TRIAL DEMANDED

EXHIBIT 1

MATTHEW COLVIN;)
JOSSEAN CRISPIN;)
ERNEST JONES;)
DANIEL RAMON;)
KERRY NAPOLEON;)
EARL HOULDEN;)
JOEL POLANCO;)
CORY CARTER;)
DWYNE HALL;)
CHRISTOPHER DORN;)
RODNEY FLOWERS;)
MILTON THOMPSON;)
TREY SCOTT;)
BRANDON ALLEN;)
MICHAEL BOLDEN;)
JACOB HUGHEY;)
WILLIAM PERRY;)
TAVARAS WILLIAMS;)
BRIAN BROWN;)
AARON JOHNSON;)
DALLIN KOCH;)
JOSEPH GWINN;)
BENJAMIN HEATH;)
JESSE OLLIS;)
MARCUS TERRELL;)
MARCO DEPETRIS;)
KEVIN FLEURIMOND;)
KERRY BAUDER;)
MATTHEW GOULD;)
CHRISTOPHER BURRUSS;)
ROBERT PARSONS;)
MICHAEL ROSENTHAL-CHESNEY;)
MATTHEW GIBSON;)
MICHAEL HOLLOWAY;)
CODY HELMICK;)
)
Plaintiffs,)
vs.)
)
JANSSEN PHARMACEUTICALS, INC.)
formerly known as ORTHO-MCNEIL-)
JANSSEN PHARMACEUTICALS, INC. and)
JANSSEN PHARMACEUTICA, INC.;)
JOHNSON & JOHNSON COMPANY aka)
JOHNSON & JOHNSON; JANSSEN)
RESEARCH AND DEVELOPMENT, LLC)
formerly known as JOHNSON & JOHNSON)
PHARMACEUTICAL RESEARCH &)
DEVELOPMENT, L.L.C.; and PATRIOT)
PHARMACEUTICALS, L.L.C.,)
)
Defendants.

PETITION

COME NOW, Plaintiffs and, if applicable, Plaintiffs' spouses, children, decedents, and/or wards who were injured and/or suffered damages on account of their or their family member's ingestion of the antipsychotic drug, Risperdal® (risperidone), in any of its forms, including Risperdal CONSTA® (a long-acting injectable form of risperidone)[1], or Invega® (paliperidone) designed, developed, tested, labeled, packaged, distributed, marketed, and sold throughout the United States by the Janssen Defendants (as defined below. Plaintiffs, by and through their attorneys, complaining of the Defendants Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.; Johnson & Johnson Company a/k/a Johnson & Johnson; Janssen Research and Development, L.L.C., f/k/a Johnson & Johnson Pharmaceutical Research and Development, L.L.C.; and Patriot Pharmaceuticals, L.L.C. (collectively referred to as "Janssen" or the "Janssen Defendants"), jointly and severally, for their causes of action against said Defendants allege and state as follows:

PLAINTIFFS

1. The "Minor Plaintiffs" referred to herein are minor children who ingested and/or were injected with the Janssen Defendants' drug products, Risperdal and/or Invega, and who, as a result of their use of Risperdal and/or Invega, developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin

[1] Risperdal, in any and all of its formulations, will be referred to as "Risperdal"

resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions. The Minor Plaintiffs are represented in these actions by one or both parents, or guardians ("Guardian Plaintiffs"), who, upon information and belief, are their next friends pursuant to Missouri Rule of Civil Procedure 55.13.

2. The "Guardian Plaintiffs" referred to herein are competent adults and the mothers, fathers and/or guardians of the Minor Plaintiffs or incapacitated Adult Plaintiffs in these actions. They bring these actions individually and on behalf of the Minor Plaintiffs or incapacitated Adult Plaintiffs to recover, among other things, medical and other expenses related to treatment resulting from their child's/ward's injuries due to their ingestion of, and/or being injected with, Risperdal and special damages.

3. The "Adult Plaintiffs" referred to herein are individuals who ingested and/or were injected with the Janssen Defendants' drug products, Risperdal and/or Invega, and who, as a result of their use of Risperdal and/or Invega, developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions.

4. "Plaintiffs" as used herein refers to the Minor Plaintiffs, Guardian Plaintiffs, and/or the Adult Plaintiffs, collectively.

5. Plaintiff Timothy Lawson is an individual citizen and resident of St. Louis, MO. Plaintiff Timothy Lawson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

6. Plaintiff Heather Senn is an individual citizen and resident of Vineland, NJ and is the mother of Minor Plaintiff **C.A.** . The aforementioned Plaintiff suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

7. Plaintiff Donnavin Negron is an individual citizen and resident of Allentown, PA. Plaintiff Timothy Lawson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

8. Plaintiff April Burks is an individual citizen and resident of Shreveport, LA and is the mother of Minor Plaintiff **E.J.** . The aforementioned Plaintiff suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

9. Plaintiff Veshandus Flemings is an individual citizen and resident of Harvey, LA and is the mother of Minor Plaintiff **E.F.** . The aforementioned Plaintiff suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

10. Plaintiff Stefanie Parker is an individual citizen and resident of Macy, NE and is the mother of Minor Plaintiff **A.P.G.** . The aforementioned Plaintiff suffered

serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

11. Plaintiff Anthony King is an individual citizen and resident of Moreno Valley, CA. Plaintiff Anthony King suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

12. Plaintiff Wilfred Holland is an individual citizen and resident of Jacksonville, FL. Plaintiff Wilfred Holland suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

13. Plaintiff Terrell McGowan is an individual citizen and resident of Springfield Gardens, NY. Plaintiff Terrell McGowan suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

14. Plaintiff Michael Note is an individual citizen and resident of Hinsdale, NH. Plaintiff Michael Note suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

15. Plaintiff Eric Taylor is an individual citizen and resident of Baltimore, MD. Plaintiff Eric Taylor suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

16. Plaintiff Latrend Woodland is an individual citizen and resident of Joppa, MD. Plaintiff Latrend Woodland suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

17. Plaintiff Laurence Jordan is an individual citizen and resident of Saint Clairsville, OH. Plaintiff Laurence Jordan suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

18. Plaintiff Robert Jones is an individual citizen and resident of Augusta, GA. Plaintiff Robert Jones suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

19. Plaintiff Leon Davis-Hubert is an individual citizen and resident of Chicago, IL. Plaintiff Leon Davis-Hubert suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

20. Plaintiff Justin Luongo is an individual citizen and resident of Aberdeen, NC. Plaintiff Justin Luongo suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

21. Plaintiff Brian Jones is an individual citizen and resident of Dayton, OH. Plaintiff Brian Jones suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

22. Plaintiff James Hatcher is an individual citizen and resident of Spring, TX. Plaintiff James Hatcher suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

23. Plaintiff Bryan Draheim is an individual citizen and resident of Mason City, IA. Plaintiff Bryan Draheim suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

24. Plaintiff Jason Moorman is an individual citizen and resident of Sugar Land, TX. Plaintiff Jason Moorman suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

25. Plaintiff Jonathon Haddix is an individual citizen and resident of Waco, TX. Plaintiff Jonathon Haddix suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

26. Plaintiff Brian Mattingly is an individual citizen and resident of Louisville, KY. Plaintiff Brian Mattingly suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

27. Plaintiff Jovan Hopings is an individual citizen and resident of Toledo, OH. Plaintiff Jovan Hopings suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

28. Plaintiff Michael Smith is an individual citizen and resident of Norfolk, VA. Plaintiff Michael Smith suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

29. Plaintiff LaMel Davis is an individual citizen and resident of New York, NY. Plaintiff LaMel Davis suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

30. Plaintiff Arron Thomas is an individual citizen and resident of Beaverton, OR. Plaintiff Arron Thomas suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

31. Plaintiff Tyshon Younge is an individual citizen and resident of New York, NY. Plaintiff Tyshon Younge suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

32. Plaintiff Paul Gilmore is an individual citizen and resident of Des Moines, IA. Plaintiff Paul Gilmore suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

33. Plaintiff Kevin Woods is an individual citizen and resident of Valdosta, GA. Plaintiff Kevin Woods suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

34. Plaintiff Nicholas Andrews is an individual citizen and resident of Adams, NE. Plaintiff Nicholas Andrews suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

35. Plaintiff Brendan Makarewicz is an individual citizen and resident of Grafton, WI. Plaintiff Brendan Makarewicz suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

36. Plaintiff Timothy Bernard is an individual citizen and resident of Orland, ME. Plaintiff Timothy Bernard suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

37. Plaintiff Dupree Hinds is an individual citizen and resident of Chicopee, MA. Plaintiff Dupree Hinds suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

38. Plaintiff Elias Ramirez is an individual citizen and resident of Farmingdale, NY. Plaintiff Elias Ramirez suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

39. Plaintiff Aleksandr Gershzon is an individual citizen and resident of San Francisco, CA. Plaintiff Aleksandr Gershzon suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

40. Plaintiff Joshua Norcott is an individual citizen and resident of Seneca Falls, NY. Plaintiff Joshua Norcott suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

41. Plaintiff Eric Hall is an individual citizen and resident of Louisville, KY. Plaintiff Eric Hall suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

42. Plaintiff Tyron Dutton is an individual citizen and resident of Parkville, MD. Plaintiff Tyron Dutton suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

43. Plaintiff Alex Harlow is an individual citizen and resident of Newton, IA. Plaintiff Alex Harlow suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

44. Plaintiff Lee Smith is an individual citizen and resident of Houston, TX. Plaintiff Lee Smith suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

45. Plaintiff Daniel Turley is an individual citizen and resident of Hampton, VA. Plaintiff Daniel Turley suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

46. Plaintiff Desmond Guillory is an individual citizen and resident of Lake Charles, LA. Plaintiff Desmond Guillory suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

47. Plaintiff Ronald Rivers is an individual citizen and resident of Arverne, NY. Plaintiff Ronald Rivers suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

48. Plaintiff Jason Stenson is an individual citizen and resident of Bronx, NY. Plaintiff Jason Stenson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

49. Plaintiff William Morris is an individual citizen and resident of Bradford, MA. Plaintiff William Morris suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

50. Plaintiff Matthew Colvin is an individual citizen and resident of Ft. Collins, CO. Plaintiff Matthew Colvin suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

51. Plaintiff Jossean Crispin is an individual citizen and resident of Waterbury, CT. Plaintiff Jossean Crispin suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

52. Plaintiff Ernest Jones is an individual citizen and resident of Fort Ogden, FL. Plaintiff Ernest Jones suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

53. Plaintiff Daniel Ramon is an individual citizen and resident of Salinas, CA. Plaintiff Daniel Ramon suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

54. Plaintiff Kerry Napoleon is an individual citizen and resident of Oakland, CA. Plaintiff Kerry Napoleon suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

55. Plaintiff Earl Houlden is an individual citizen and resident of Silver Springs, NV. Plaintiff Earl Houlden suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

56. Plaintiff Joel Polanco is an individual citizen and resident of Brooklyn, NY. Plaintiff Joel Polanco suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

57. Plaintiff Cory Carter is an individual citizen and resident of Cleveland, OH. Plaintiff Cory Carter suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

58. Plaintiff Dwyne Hall is an individual citizen and resident of Philadelphia, PA. Plaintiff Dwyne Hall suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

59. Plaintiff Christopher Dorn is an individual citizen and resident of Reisterstown, MD. Plaintiff Christopher Dorn suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

60. Plaintiff Rodney Flowers is an individual citizen and resident of Erick, OK. Plaintiff Rodney Flowers suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

61. Plaintiff Milton Thompson is an individual citizen and resident of San Angelo, TX. Plaintiff Milton Thompson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

62. Plaintiff Trey Scott is an individual citizen and resident of Adams Run, SC. Plaintiff Trey Scott suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

63. Plaintiff Brandon Allen is an individual citizen and resident of Simi Valley, CA. Plaintiff Brandon Allen suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

64. Plaintiff Michael Bolden is an individual citizen and resident of Parkville, MD. Plaintiff Michael Bolden suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

65. Plaintiff Jacob Hughey is an individual citizen and resident of Denton, TX. Plaintiff Jacob Hughey suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

66. Plaintiff William Perry is an individual citizen and resident of Denton, TX. Plaintiff William Perry suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

67. Plaintiff Tavaras Williams is an individual citizen and resident of Norfolk, VA. Plaintiff Tavaras Williams suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

68. Plaintiff Brian Brown is an individual citizen and resident of Whitfield, MS. Plaintiff Brian Brown suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

69. Plaintiff Aaron Johnson is an individual citizen and resident of Leicester, NC. Plaintiff Aaron Johnson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

70. Plaintiff Dallin Koch is an individual citizen and resident of Evansville, IN. Plaintiff Dallin Koch suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

71. Plaintiff Joseph Gwinn is an individual citizen and resident of Nanty Glo, PA. Plaintiff Joseph Gwinn suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

72. Plaintiff Benjamin Heath is an individual citizen and resident of New Orleans, LA. Plaintiff Benjamin Heath suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

73. Plaintiff Jesse Ollis is an individual citizen and resident of Morganton, NC. Plaintiff Jesse Ollis suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

74. Plaintiff Marcus Terrell is an individual citizen and resident of Elizabeth, NJ. Plaintiff Marcus Terrell suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

75. Plaintiff Marco DePetris is an individual citizen and resident of Bronx, NY. Plaintiff Marco DePetris suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

76. Plaintiff Kevin Fleurimond is an individual citizen and resident of Brooklyn, NY. Plaintiff Kevin Fleurimond suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

77. Plaintiff Kerry Bauder is an individual citizen and resident of Lansford, PA. Plaintiff Kerry Bauder suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

78. Plaintiff Matthew Gould is an individual citizen and resident of Houston, TX. Plaintiff Matthew Gould suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

79. Plaintiff Christopher Burruss is an individual citizen and resident of Greenville, TX. Plaintiff Christopher Burruss suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

80. Plaintiff Robert Parsons is an individual citizen and resident of Beaverton, MI. Plaintiff Robert Parsons suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

81. Plaintiff Michael Rosenthal-Chesney is an individual citizen and resident of Phoenix, AZ. Plaintiff Michael Rosenthal-Chesney suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

82. Plaintiff Matthew Gibson is an individual citizen and resident of Saint Louis, MO. Plaintiff Matthew Gibson suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

83. Plaintiff Michael Holloway is an individual citizen and resident of Las Vegas, NV. Plaintiff Michael Holloway suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

84. Plaintiff Cody Helmick is an individual citizen and resident of Lake Forest, CA. Plaintiff Cody Helmick suffered serious injury and damages that were caused or contributed to by Defendants' defective and dangerous products.

DEFENDANTS

85. Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. ("Janssen Pharma"), is a Pennsylvania corporation with its principal place of business in New Jersey. Janssen Pharma is duly qualified to do business in the State of Missouri, and maintains a registered agent in the State of Missouri. Janssen Pharma does business in the State of Missouri and other states by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Risperdal and/or Invega. Moreover, Janssen Pharma has transacted business and committed torts in the State of Missouri that gave rise to this action. On information and belief, Janssen Pharma is a wholly-owned subsidiary of Defendant Johnson & Johnson.

86. At all times mentioned herein, Janssen Pharma was responsible for Risperdal and/or Invega. From time to time, the name of the entity has changed.

87. On information and belief, Johnson & Johnson is a fictitious name adopted by Defendant Johnson & Johnson Company a/k/a Johnson & Johnson (hereinafter, "Johnson & Johnson"), a New Jersey corporation with its principal place of business in New Jersey. Johnson & Johnson does business in the State of Missouri and throughout the United States by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Risperdal and/or Invega. Moreover, Johnson & Johnson has transacted business and committed torts in the State of Missouri that gave rise to this action.

88. On information and belief, Janssen Research and Development, LLC, f/k/a Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("JJPRD") is a New Jersey limited liability company that has offices in Spring House, Pennsylvania and Exton, Pennsylvania. JJPRD was responsible for clinical research and development of Risperdal and/or Invega, for pharmacovigilance in the United States pertaining to Risperdal and/or Invega, and for submitting regulatory reports to the United States Food & Drug Administration ("FDA") pertaining to Risperdal and/or Invega. JJPRD does business in the State of Missouri and throughout the United States by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Risperdal and/or Invega. Moreover, JJPRD has transacted business and committed torts in the State of Missouri that gave rise to this action.

89. On information and belief, Defendant Patriot Pharmaceuticals L.L.C. ("Patriot") is a Pennsylvania limited liability corporation, located at 200 Tournament Drive, Horsham Pennsylvania, 19044. Patriot does business in the State of Missouri and throughout the United

States by, among other things, the labeling, distributing, marketing, selling and/or profiting from the authorized generic pharmaceutical, risperidone. Moreover, Patriot has transacted business and committed torts in the State of Missouri that gave rise to this action.

90. Patriot admits it is a wholly-owned subsidiary of Janssen Pharmaceuticals, Inc. *See* http:/www.patriotpharmaceuticals.com/patriotpharmaceuticals/about.html.

91. Patriot engages in the labeling, distributing, marketing and/or selling of the authorized generic pharmaceutical, risperidone. *See id*.

92. On its website, Patriot touts its close relationship with the Johnson & Johnson "Family of Companies":

> We work closely with JOM Pharmaceutical Services, Inc. with locations in Somerset, NJ, and Shepherdsville, KY, to fill customer orders and distribute our products. We also work closely with Johnson & Johnson Health Care Systems Inc. of Piscataway, NJ, to manage supply agreements and contracts that we have with our trade customers.

See id.

93. Janssen Pharma, Johnson & Johnson, JJPRD and Patriot will, at times, be referred to collectively herein as "The Janssen Defendants" or "Janssen."

94. Several affiliates have provided Janssen Pharma and the other Janssen Defendants with support in the development and distribution of Risperdal and/or Invega. These affiliates include Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Ortho-McNeil Pharmaceuticals, Inc., Janssen Ortho-McNeil Pharmaceutica Services, Pharmaceutical Sourcing-Group Americas, Pharmaceutical Group Strategic Marketing, Janssen Pharmaceutica N.V., Janssen Ortho LLC, Janssen Medical Affairs, L.L.C., and Ortho-McNeil Janssen Scientific Affairs LLC. All of these entities are subsidiaries or divisions of Defendants Janssen Pharma

and/or Johnson & Johnson, do business in the State of Missouri, and have transacted business in the State of Missouri and committed torts in the State of Missouri that gave rise to this action.

95. Plaintiffs are informed and believe and based thereupon allege that at all times herein mentioned each of the Defendants was the agent, servant and/or employee or occupied other relationships with each of the other named Defendants and at all times herein mentioned acted within the course and scope of said agency and/or employment and/or other relationship and each other Defendant has ratified, consented to, and approved the act of his agents, employees, and representatives, and that each actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Petition.

96. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiffs. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiffs for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

VENUE AND JURISDICTION

97. All Plaintiffs herein are properly joined pursuant to Rule 52.05(a) of the Missouri Rules of Civil Procedure, as their claims all arise out of the same series of transactions or occurrences. The claims in this case present common questions of fact and law concerning, among other things, what information Defendants possessed concerning the harmful effects of Risperdal and/or Invega, what information it disclosed to patients and physicians about those harmful effects, and what information Defendants were required by law to disclose about those harmful effects. Plaintiffs' claims are all logically related in that all Plaintiffs claim that Risperdal and/or Invega was defectively designed, manufactured and marketed by Defendants,

and that Defendants failed to provide adequate warnings regarding the dangers posed by Risperdal and/or Invega use. All Plaintiffs suffered medically similar injuries as result of the same wrongful conduct and tortuous acts by the Defendants, including, but not limited to, the Defendants' failure to conduct adequate safety and efficacy studies, the Defendants' distribution of inadequate and misleading marketing materials and literature to physicians and patients, and the lack of adequate warnings provided to physicians and patients. Defendants' wrongful conduct and tortuous acts were done without any regard for individual Plaintiff differences. Defendants' conduct in designing, developing, marketing, and distributing Risperdal and/or Invega relates to all Plaintiffs' claims herein and makes up a common universe of facts underlying the Plaintiffs' claims.

98. Venue is proper in this Court pursuant to Mo. Rev. Stat. 508.010 because Plaintiff Timothy Lawson was first injured by Risperdal and/or Invega® in the City of St. Louis. At all pertinent times, Timothy Lawson used Risperdal and/or Invega® in the City of St. Louis, and Timothy Lawson was first injured while in the City of St. Louis.

99. At all pertinent times, Defendants have conducted and continue to conduct continuous and systematic business in the State of Missouri, have purposefully injected their products, including Risperdal and/or Invega, into the stream of commerce to be sold in Missouri, and have taken actions such that they should anticipate being sued in the State of Missouri.

100. Defendants have transacted business in the State of Missouri that has given rise to this cause of action, maintained registered agents in the State of Missouri, and have committed torts in whole or in part in the State of Missouri, including torts giving rise to this action. This includes the marketing and selling of Risperdal and/or Invega in the State of Missouri, which gave to this cause of action as a whole.

101. There is no federal subject matter jurisdiction because no federal question is raised and some of the Plaintiffs and the Defendants are citizens of the same state, i.e., New Jersey, Pennsylvania, and Missouri.

102. Plaintiffs have suffered injuries and damages arising out of the use of the antipsychotic medications -- Risperdal and/or Invega.

103. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has in personal jurisdiction over the Defendants, because Defendants are present in the State of Missouri such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

104. This Court has personal jurisdiction over the Defendants pursuant to and consistent with Missouri's long arm statute (R.S.Mo §506.500) and the Constitutional requirements of Due Process in that the defendants acting through their agents or apparent agents, committed one or more of the following:

(a) The transaction of any business within this state;

(b) The making of any contract within this state;

(c) The commission of a tortious act within this state;

(d) The ownership, use, or possession of any real estate situated in this state;

(e) The contracting to insure any person, property or risk located within this state at the time of contracting.

105. Requiring Defendants to litigate this claim in Missouri does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

106. The Plaintiff's claims arise out of Defendants' design and marketing of pharmaceutical products in the State of Missouri.

107. These Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, *inter alia*, the State of Missouri.

108. Additionally, certain Plaintiffs herein were first injured from the Defendants' products in the City of St. Louis, including Plaintiff Cecil Keen. Plaintiff Cecil Keen was first prescribed and ingested Risperdal® in the City of St. Louis, Missouri. Plaintiff Cecil Keen developed the signature injuries complained of herein while a resident of the City of St. Louis, Missouri. Accordingly, venue is proper under R.S.Mo §508.010.

109. This Court has jurisdiction over Defendant Janssen Pharma, a wholly-owned subsidiary of Defendant Johnson & Johnson, because Janssen Pharma committed torts in whole or in part in the State of Missouri, has had systematic and continuous contacts with the State of Missouri, specifically within the City of St. Louis, has agents and representatives which can be found in this City of St. Louis, and/or has otherwise engaged in misconduct in this City of St. Louis. Defendant is amenable to service by a Missouri court and the exercise of jurisdiction over it comports with due process.

110. This Court has jurisdiction over Defendant JJPRD, a New Jersey limited liability company, because JJPRD conducts substantial business in the State of Missouri, committed torts in whole or in part in the State of Missouri, and has systematic and continuous contacts with the State of Missouri.

111. This Court has jurisdiction over Defendant Johnson & Johnson, a New Jersey corporation, because Defendant Johnson & Johnson conducts substantial business in the State of Missouri, committed torts in whole or in part in the State of Missouri, has systematic and continuous contacts with the State of Missouri, has agents and representatives which can be found in this State, and/or has otherwise engaged in conduct subjecting said Defendant to the

reach of the applicable long-arm statute. Said Defendant is subject to service by a Missouri court, and the exercise of jurisdiction over said Defendant comports with due process.

112. This Court has jurisdiction over Defendant Patriot, a Pennsylvania corporation, because Defendant Patriot conducts substantial business in the State of Missouri, committed torts in whole or in part in the State of Missouri, has systematic and continuous contacts with the State of Missouri, has agents and representatives which can be found in this State, and/or has otherwise engaged in conduct subjecting said Defendant to the reach of the applicable long-arm statute. Said Defendant is subject to service by a Missouri court, and the exercise of jurisdiction over said Defendant comports with due process.

113. This Court has jurisdiction over Defendant RELX Elsevier because RELX conducts substantial business in the State of Missouri, committed torts in whole or in part in the State of Missouri, has systematic and continuous contacts with the Missouri, has agents and representatives which can be found in this State, and/or has otherwise engaged in conduct subjecting said Defendant to the reach of the applicable long-arm statute. Said Defendant is subject to service by a Missouri court, and the exercise of jurisdiction over said Defendant comports with due process.

114. This suit is brought to recover damages and other relief, and the costs of suit, including reasonable attorney and expert fees, for the damages Plaintiffs have sustained as a result of Defendants' acts and omissions, Plaintiffs each individually seek relief that is within the jurisdictional limits of the Court in an amount in excess of Twenty-Five Thousand Dollars ($25,000.00).

JOINDER OF PLAINTIFFS

115. Joinder of Plaintiffs in this Petition is proper pursuant to R.S.Mo §507.040 (1) because Plaintiffs' right to relief arise out of the same transaction, occurrence, or series of transactions or occurrences and involve common questions of law and fact. Specifically, all of the Plaintiffs herein claim injuries and damages arising from ingestion of the same drug, Risperdal®. All of the Plaintiffs claims arise from a series of transactions involving the Defendants and common questions of law and fact will arise.

GENERAL ALLEGATIONS

Risperdal and Invega Products

116. At all relevant times, the Janssen Defendants, through their agents, servants, and employees, were the designer(s), developer(s), manufacturer(s), marketer(s), advertiser(s), distributor(s), and/or seller(s) of the brand name prescription drugs, Risperdal and/or Invega.

117. Risperdal is an antipsychotic medication, belonging to a class of drugs which have become known as "atypical" or "second generation" ("SGA") antipsychotics. Other atypical antipsychotics include Clozaril (clozapine), Seroquel (quetiapine), Zyprexa (olanzapine), Geodon (ziprasidone), Abilify (aripiprazole), and Invega (paliperidone) (the active ingredient of which is 9-hydroxy-risperidone, the active metabolite of risperidone), all of which began coming onto the market in 1989.

118. Risperdal was originally developed and approved for use in the treatment of symptoms associated with schizophrenia. However, Risperdal does not cure schizophrenia or any other mental health condition. The pharmacologic action of Risperdal is unknown but is thought to be dependent on its ability to block or moderate the level of dopamine, a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations.

119. Risperdal and/or Invega can and do cause serious and sometimes fatal injuries to the metabolic, cerebrovascular, neurologic, and endocrine systems and to organs such as the brain, liver, and pancreas in some patients. Adverse effects include, but are not limited to, rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, and/or other related conditions. Complications of diabetes mellitus include ketoacidosis, hyperosmolar coma, heart disease, infection, neuropathy, blindness, seizures, and death.

120. The branded version of Risperdal earned Janssen $2.5 billion in 2007, the last full year for which Janssen enjoyed patent protection for Risperdal. The before-mentioned $2.5 billion accounted for more than 6% of Johnson & Johnson's company-wide sales.

Authorized Generic Version of Risperidone

121. On June 30, 2008, the Janssen Defendants announced their launch of an authorized generic version of risperidone through their subsidiary, Patriot Pharmaceuticals, L.L.C.

122. Patriot refers to itself as "A Distributor of Authorized Generic Pharmaceutical Products." *See* http://www.patriotpharmaceuticals.com/patriotpharmaceuticals/about.html.

123. The term "authorized generic" refers to a pharmaceutical product that is produced by innovator (brand) companies under a New Drug Application (NDA), and marketed and

distributed by, an authorized generic distributor like Patriot with a generic product label. *See* http://www.patriotpharmaceuticals.com/patriotpharmaceuticals/faqs.html#Q1.

124. The generic drugs distributed by Patriot are authorized for sale to customers by the NDA holder of the innovator product.

125. According to Patriot itself, the "family of products [distributed by Patriot] is made by the same manufacturers that are approved in the NDAs of the innovator products." *See id.* Accordingly, the risperidone distributed by Patriot is manufactured by Janssen itself.

126. Upon information and belief, the authorized generic versions of risperidone were released under NDA numbers 020272, 020588, and 021444, held by the Janssen Defendants for Risperdal products.

127. Upon information and belief, Janssen manufactures for Patriot, and Patriot distributes Risperidone in the following forms: .25 mg. tablets, .5 mg tablets, 1 mg tablets, 2 mg tablets, 3 mg tablets, 4 mg tablets and oral solution.

128. The authorized generic is the approved NDA brand name product labeled as a generic and marketed at a price competitive with traditional generics (traditional generics are licensed under Abbreviated New Drug Applications (ANDA) held by generic manufacturers). Because the authorized generic Risperidone is licensed under the original NDA held by Janssen Defendants, the Janssen Defendants retain control over the design, development, testing, labeling, packaging, distribution, and marketing of their "generic" product. The Janssen Defendants thus benefit from the sale of a "generic" product in addition to the brand product, after patent protection is lost.

False and Misleading Promotional Activities

129. Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") (21 U.S.C. §§ 352(a) and 321(n)) require Janssen to fully and accurately disclose information relating to hyperprolactinemia, gynecomastia, hyperglycemia, diabetes mellitus, ketoacidosis, tardive dyskinesia and other adverse effects in the Risperdal and/or Invega package insert (PI) and other labeling, and to include adequate warnings concerning these and other risks in promotional materials for Risperdal and/or Invega.

130. Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) prohibit Janssen from minimizing these risks, and from promulgating misleading claims that Risperdal and/or Invega is safer than other antipsychotic medications on the market.

131. Janssen has violated, and continues to violate, Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) by omitting information concerning these risks from the Risperdal and/or Invega Package Insert ("PI") and other labeling, and by utilizing and/or distributing promotional materials that were false and misleading in that they minimized the risks of these serious adverse events, failed to advise physicians to monitor patients for these adverse events, and otherwise falsely claimed that Risperdal and/or Invega was safer and more efficacious than other antipsychotic medications on the market.

132. On information and belief, Janssen engaged in promotional activities that were not only false and misleading as to the safety and efficacy of Risperdal and/or Invega, but, in many cases, were designed to illegally expand the use of Risperdal and/or Invega for off-label uses, without scientific proof of drug products' safety and efficacy in treating such disorders, so as to increase sales and profits at the expense of the safety, health, and well-being of the public, including Plaintiffs, by means of the following, including, but not limited to:

(a) Manipulating clinical trials to produce results favorable to Risperdal and/or Invega;

(b) Failing to publish or report negative studies concerning Risperdal and/or Invega, to the FDA or to publish results in the medical literature;

(c) Ghostwriting medical journal articles, pertaining to Risperdal and/or Invega, i.e., utilizing hired medical writers, who are not researchers or scientists, to write articles and then submitting them to selected opinion or "thought" leaders to attach their names to them as authors without making any meaningful contribution to the article, to lend false credence to these articles;

(d) Presenting false and misleading studies and reports concerning Risperdal and/or Invega at professional meetings by means of posters and abstracts;

(e) Publishing the same studies and/or selected portions of the same studies in multiple journals to create a false impression of scientific acceptability of Risperdal and/or Invega for a variety of uses (a practice known as "salami science");

(f) Failing to file accurate and timely reports of adverse events and abnormal laboratory values seen in Risperdal and/or Invega clinical trials with the FDA;

(g) Failing to publish accurate reports of adverse events and abnormal laboratory values in articles concerning Risperdal and/or Invega clinical trials;

(h) Failing to file accurate and timely reports of post-marketing adverse events with the FDA;

(i) Failing to publish accurate reports of post-marketing adverse events in articles concerning Risperdal and/or Invega;

(j) Failing to recognize signal evidencing association between Risperdal and/or Invega and adverse events in post-marketing adverse event reports;

(k) Conducting marketing and promotion of Risperdal and/or Invega for off-label use under the guise of continuing medical education;

(l) Utilizing "advisory boards" to conduct marketing and promotion of Risperdal and/or Invega;

(m) Paying large sums to key opinion leaders to tout Risperdal and/or Invega as treatment for a variety of disorders;

(n) Marketing Risperdal and/or Invega as "broad spectrum" antipsychotics;

(o) Hiring consultants involved in creating treatment algorithms in order to achieve favorable treatment of Risperdal and/or Invega in those algorithms;

(p) Giving lucrative contracts for "clinical research" as a reward to high prescribers of Risperdal and/or Invega;

(q) Distributing promotional materials such as sales aids, journal ads, display panels, brochures, letters, flashcards, calendars, and computer programs regarding Risperdal and/or Invega which were false, misleading, and/or lacking in fair balance; and

(r) Coordinating, with consultants, marketing executives, medical staff, healthcare professionals and scientists, to off-label market and promote Risperdal for the treatment of the following off-label uses in children: Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, and pervasive development disorders (PDD), among others.

History of Risperdal Label Changes and FDA's Reprimands to Janssen

Schizophrenia and Bipolar Disorder

133. On December 29, 1993, Janssen obtained approval from the FDA to market Risperdal oral tablets for the treatment of "manifestations of psychotic disorders" (schizophrenia) in adults with a target dosage of 4 to 6 milligrams per day.

134. In September 2000, the FDA requested that the label be changed to more clearly indicate that Risperdal was only approved for use in treating schizophrenia in adults.

135. The Janssen Defendants delayed making this recommended change until two years later, in 2002.

136. The FDA subsequently approved Risperdal in other formulations for the treatment of schizophrenia in adults ─ on June 10, 1996, the FDA approved Risperdal oral solution; on

April 2, 2003, the FDA approved the Risperdal M-Tab for adults; and on October 29, 2003 the FDA approved Risperdal Consta®, a long-acting injection of Risperdal.

137. On December 4, 2003, the FDA approved additional uses of Risperdal oral tablets, Risperdal oral solution and Risperdal M-Tab as monotherapy for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder, and as combination therapy, with Lithium or Valproate, for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults.

Irritability in Autistic Disorder

138. In October 2006, Risperdal was approved for the treatment of irritability associated with autistic disorder in children and adolescents (between the ages of 5 and 16), including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums and quickly changing moods. Risperdal has only been approved for the treatment of irritability associated with autistic disorder in children and adolescents, and not the whole Autistic Spectrum Disorder – *i.e.*, the wider variation of autistic symptoms including withdrawal from social interactions, problems communicating, and repetitive behaviors. Risperdal has not been approved for children younger than 5 or those older than 16 years for irritability associated with autistic disorder.

Schizophrenia and Mania Associated with Bipolar I in Children and Adolescents

139. On August 22, 2007, Risperdal received approval from the FDA for the treatment of schizophrenia in adolescents ages 13-17 years, and for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in children and adolescents ages 10-17 years.

FDA Communications

140. In January 1999, the FDA sent a letter to Janssen regarding promotional materials and activities for the marketing of Risperdal Tablets that had been reviewed by the Division of Drug Marketing, Advertising and Communications ("DDMAC") as part of its monitoring and surveillance program. In particular, the DDMAC letter concerned a campaign that marketed Risperdal for use in geriatric patients. These materials included, but were not limited to, sales aids, journal ads, a display panel, brochures, and a letter, a flashcard, a calendar, and a computer program, which DDMAC concluded were false, misleading, and/or lacking in fair balance, and in violation of the FDCA and the regulations promulgated thereunder.

141. As of July 1999, the Risperdal label still contained no warnings concerning diabetes mellitus or hyperglycemia. Under the "adverse reactions" section, the label mentioned that micturition disturbances and weight gain were twice as common with Risperdal-treated patients as for placebo-treated patients. Under the section entitled, "Other Events Observed During Pre- Marketing Clinical Trials," the label stated that there was a positive ($p<0.5$) trend for weight gain with the percentage of patients having weight change of at least 7% body weight being 18% for Risperdal vs. 9% for placebo. The only place in the label at that time that even mentioned diabetes mellitus was on page 19 of 24, under "other events" and "metabolic and nutritional disorders," and no indication of any association with Risperdal or the true severity or frequency of diabetes mellitus or hyperglycemia or the need for blood glucose monitoring was mentioned.

142. Concerned about the lack of adequate studies to support the ever-expanding uses being promoted by the Janssen defendants for Risperdal, in September 2000, the FDA requested that the Janssen Defendants change the indication in the labeling and package insert for

Risperdal to more clearly state that the only approved use for Risperdal was in the "treatment of schizophrenia" in adults. Despite repeated requests from the FDA, the Janssen Defendants refused to make this change until 2002.

143. As early as 2001, at the FDA's insistence, the label for Risperdal was modified to include a statement that "The safety and effectiveness in children have not been established." However, Defendants continued to actively market and promote Risperdal and/or Invega for off label uses in children.

144. On information and belief, despite the addition of language to the Risperdal label designed to restrict off-label and scientifically unproven and potentially dangerous uses of Risperdal, Janssen continued to promote the off-label, unapproved use of Risperdal for children as young as 3 years of age, for a variety of unapproved uses, including but not limited to, autism, Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, Post-Traumatic Stress Disorder (PTSD), pervasive development disorders (PDD), and other conditions by the afore-mentioned means.

145. In November 2002, the FDA approved a label change providing for the addition of the term "hyperglycemia" to the "ADVERSE REACTIONS: Post-Introduction Reports" section of the Risperdal label. Prior to that there was no mention of hyperglycemia in post-marketing reports in the Risperdal label. This deliberate exclusion of the existence of case reports of hyperglycemia in no way constituted an adequate warning to prescribers or consumers regarding the true risk of diabetes mellitus with Risperdal.

146. In 2003, a researcher at the FDA identified 131 distinct cases of risperidone associated diabetes or hyperglycemia in the FDA spontaneous reporting database. A total of

seven cases appeared in three publications. Of the patients with risperidone-associated hyperglycemia (monotherapy), seventy-eight (78) had newly diagnosed hyperglycemia, forty-six (46) had exacerbation of preexisting disease, and seven (7) could not be classified. Janssen never warned the FDA, physicians or consumers of the mounting number of reported cases of diabetes or hyperglycemia or that these case reports were associated with Risperdal.

147. In September 2003, the FDA required that a "WARNING" be added to the label for all atypical antipsychotics, including Risperdal, regarding the association of hyperglycemia and diabetes with this class of drugs and the need for medical monitoring of certain patients.

148. Although the new warning was approved in November 2003, Janssen did not add the warning to the Risperdal label until January 2004.

149. On November 10, 2003, Janssen sent a false and misleading "Dear Healthcare Provider Letter" (the "DHCPL Letter") to all health care professionals likely to prescribe Risperdal that deliberately minimized the risk of hyperglycemia and diabetes and omitted the warning to monitor certain patients on Risperdal.

150. On April 19, 2004, DDMAC issued a Warning Letter to Janssen concerning the false and misleading DHCPL Letter and required Janssen to send out a new letter with corrections (the "FDA Warning Letter").

151. According to the FDA, the DHCPL Letter "misleadingly omits material information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation, in violation of Sections 502(a) and 201(n) of the Act (21 U.S.C. §§ 352(a) and 321(n)."

152. In response to the FDA Warning Letter, Janssen, on April 28, 2004, submitted a revised "Dear Healthcare Provider Letter" to the FDA for review, as well as an action plan to "address the issues raised in the [FDA] Warning letter."

153. However, the FDA, on May 27, 2004, rejected Janssen's "proposed corrective DHCP letter" and told Janssen that the letter did not "adequately address the issues raised in DDMAC's April 19, 2004 Warning Letter."

154. In response to the second FDA letter, Janssen mailed, on July 21, 2004, a revised Dear Health Care Provider letter, admitting that the previous letter omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the FDCA.

155. Prior to and during the time that Plaintiffs ingested and/or were injected with Risperdal, Janssen knew or should have known about articles written by independent researchers and published in peer-reviewed scientific journals that reported epidemiological studies as well as case reports related to Risperdal that demonstrated an association between atypical antipsychotics, including Risperdal, and serious and life-threatening adverse effects, including, but not limited to: new onset or aggravation of diabetes mellitus and development of dangerously high blood sugar levels, i.e. hyperglycemia; glucose dysregulation; ketoacidosis; pancreatitis; weight gain; hyperprolactinemia; gynecomastia, particularly in boys; and tardive dyskinesia, a serious movement disorder which can lead to permanent disability and disfigurement. Janssen, however, failed and refused to include this information in Risperdal labeling.

156. On information and belief, the Janssen Defendants pushed back vigorously in response to any article critical of Risperdal, utilizing key opinion leaders friendly to Risperdal and Janssen as surrogates to submit correspondence attacking such articles.

157. Despite problems with efficacy and safety, the Janssen Defendants and their network of supporters promoted the on-label and off-label use of Risperdal.

158. On information and belief, the Janssen Defendants failed and refused to timely and properly report information concerning spontaneous adverse event reports to the FDA, physicians, and consumers.

159. The Janssen Defendants knew, or in the exercise of reasonable diligence should have known, that the risk of new-onset diabetes mellitus or hyperglycemia associated with Risperdal and/or Invega is significantly higher than with older, cheaper, equally effective "typical" antipsychotic drugs, such as haloperidol and perphenazine.

160. The Janssen Defendants' marketing efforts were designed and implemented to create the false impression in physicians' minds that Risperdal and/or Invega are safe and effective for their patients, and that they are more efficacious and carry a lower risk of harmful side effects and adverse reactions than other available treatments.

FDA Prohibition of Off-Label Marketing and Promotion

161. "Off-label" prescribing of drugs occurs when a drug is prescribed by a medical professional for use beyond those contained in the drug's FDA-approved uses. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g. treating a child with the drug when the drug is approved to treat adults).

162. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21 U.S.C. § 360aaa(b) and (c).

163. Under the FDA laws and regulations, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which, by definition, includes all drug manufacturer promotional and advertising material) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

164. Anticipating that pharmaceutical companies would attempt to circumvent the prohibition against directly marketing and promoting a drug's off-label uses, Congress and the FDA also prohibited manufacturers from employing indirect methods to accomplish the same end.

165. Specifically, Congress and the FDA promulgated laws and regulations designed to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that advocate off-label uses of their drugs.

166. With regard to the first practice, disseminating written information, the FDA permits a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6.

167. In any other circumstance, a manufacturer cannot disseminate information concerning the off-label uses of a drug to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or federal and state government agencies unless such information is fair and balanced and the manufacturer meets the following conditions:

(a) The information concerns a drug that has been approved, licensed and cleared for marketing by the FDA;

(b) The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that pertains to a clinical investigation involving the drug and that is considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness;

(c) The information does not pose a significant risk to the public health;

(d) The information is not false or misleading; and

(e) The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer.

168. With regard to the second practice – manufacturer involvement in CME programs – the FDA's examination of these practices led to the publication of an agency enforcement policy in 1997, entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id*. The promotion of off-label drug uses at a CME program which fails the test of "independence" violates Congress' off-label marketing restrictions.

169. Off-label uses of Risperdal continue to increase. According to a 2006 analysis published in the Archives of Internal Medicine (*see Boost for Off-Label Drug Use*, Wall Street

Journal, February 16, 2008) Risperdal was used off-label 66% of the time in 2006. Today, according to published market research data, as much as 70% of the prescriptions for Risperdal are for off-label use. Off-label prescribing has clearly propelled Risperdal sales.

170. On information and belief, the Janssen Defendants have used similar tactics to promote Invega for off-label uses.

171. On information and belief, the Janssen Defendants materially violated the laws and regulations governing off-label promotional activities, labeling and misbranding as well as the applicable standard of care in promoting use of Risperdal and/or Invega for unapproved uses in adults, in children and adolescents, and in the elderly by improperly disseminating medical and scientific publications concerning off-label uses of Risperdal and/or Invega and support for CME programs that advocated off-label uses of Risperdal and/or Invega.

PLAINTIFFS' USE OF DRUG PRODUCTS

172. The Adult Plaintiffs and the Minor Plaintiffs were prescribed, ingested and/or were injected with Risperdal and/or Invega at various times.

173. While using said drug product, and as a direct and proximate result thereof, the Adult Plaintiffs and the Minor Plaintiffs developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement

disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions.

174. As a result of said injuries, Plaintiffs have suffered significant bodily and mental injury, pain and suffering, mental anguish, disfigurement, embarrassment, and inconvenience, have been caused to incur past and future medical expenses, will be required in some cases to undergo mastectomy (surgery) to remove the breasts, and will suffer loss of earning capacity in the future.

175. The Adult Plaintiffs and the Minor Plaintiffs used Risperdal and/or Invega manufactured and distributed by Janssen that had reached the Adult Plaintiffs and the Minor Plaintiffs without substantial change in said drug product's condition since the drugs were manufactured or sold.

176. On information and belief, the Adult Plaintiffs' and the Minor Plaintiffs' prescribing physicians would not have prescribed Risperdal and/or Invega to Adult Plaintiffs and the Minor Plaintiffs had the Janssen Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the ingestion of Risperdal and/or Invega and the fact that there were not adequate well-controlled studies showing that Risperdal and/or Invega were safe and effective for treatment of Adult Plaintiffs' and the Minor Plaintiffs' condition, and had said physician not received information and promotional materials from the Janssen Defendants suggesting that Risperdal and/or Invega were safe and effective for use in treating children and adolescents or in treating Plaintiffs' condition. Further, Plaintiffs' prescribing physicians would have changed the way in which they treated the condition for which Plaintiffs were being treated, would have warned patients, including Plaintiffs, about the signs and symptoms of serious adverse effects of Risperdal and/or Invega, would have discussed

the risks of weight gain, hyperglycemia, diabetes mellitus, hyperprolactinemia, gynecomastia, and tardive dyskinesia and other serious adverse events, and would have permitted patients to choose whether to be treated with Risperdal and/or Invega or not after considering the risks, and, if the patients decided to take Risperdal and/or Invega, Plaintiffs' prescribing physician would have more effectively monitored the Plaintiffs' physical appearance and weight, and would have performed or requested regular physical examinations and laboratory tests, while Plaintiffs were on Risperdal and/or Invega had said Defendants appropriately and adequately disclosed the risks of weight gain, diabetes mellitus, hyperprolactinemia, gynecomastia, and tardive dyskinesia, and death associated with Risperdal and/or Invega and/or had the Janssen Defendants appropriately and adequately warned of the need for initial and/or periodic monitoring of patients on Risperdal and/or Invega.

177. Plaintiffs would not have taken, and Plaintiffs' parents or guardians would not have allowed Plaintiffs to take, Risperdal and/or Invega if the Janssen Defendants had properly disclosed the risks associated with Risperdal and/or Invega, and Plaintiffs and/or Plaintiffs' parents or guardians would have requested and/or followed the prescribing physicians' advice as to the risks and benefits of Risperdal and/or Invega, and/or requested and/or obtained initial and/or regular examinations and blood monitoring had the Janssen Defendants appropriately and adequately warned of the risks and the need for initial and/or regular monitoring of patients taking Risperdal and/or Invega.

178. Plaintiffs have performed all conditions precedent to the bringing of each of the causes of action described herein below.

179. At all relevant times, Janssen was under a continuing duty under federal law and parallel state laws to disclose the true character, quality, and nature of the increased risks and

dangers associated with Risperdal®.

180. As a result of Janssen's concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

181. Janssen furthered their fraudulent concealment through act and omission, including misrepresenting known dangers and/or defects in Risperdal® and/or arising out of the use of Risperdal® and a continued and systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

182. Janssen's acts and omissions, before, during and/or after the act causing Plaintiffs' injury, prevented Plaintiffs and/or Plaintiffs physicians from discovering the injury or cause thereof until recently.

183. Janssen's conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

FRAUDLUENT CONCEALMENT AND DISCOVERY RULE

184. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

185. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants. Plaintiffs have been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

186. Plaintiffs could not reasonably have discovered the injury and its cause until shortly before the initiation of these actions.

187. Defendants were under a continuing duty to disclose the true character, quality and nature of Risperdal and/or Invega to the Plaintiffs. Because of their concealment of the true character, quality, and nature of Risperdal and/or Invega to Plaintiffs, Defendants are estopped from relying on any statues of limitations defense.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

188. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

189. The Janssen Defendants had a duty to exercise reasonable care in the design, development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and post-marketing safety monitoring of Risperdal and/or Invega, including a duty to insure that the products did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

190. The Janssen Defendants failed to perform adequate testing concerning the safety of Risperdal and/or Invega which would have shown that Risperdal and/or Invega posed a serious risk of rapid weight gain, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other adverse effects which would have permitted adequate and appropriate warnings to have been given by Janssen to prescribing physicians and the consuming public, including Plaintiffs.

191. The Janssen Defendants failed to effectively warn users and physicians that nonpharmacological intervention and/or other medications, including other atypical antipsychotic medications, should be the first or exclusive method of treating Plaintiffs' condition.

192. The Janssen Defendants were negligent in the design, development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and post-marketing safety monitoring of Risperdal and/or Invega in that, among other things, they:

(a) Failed to design Risperdal and/or Invega so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

(b) Failed to develop Risperdal and/or Invega properly so as to minimize the proliferation of new uses for which there was little or no scientific evidence of safety and efficacy;

(c) Failed to manufacture Risperdal and/or Invega properly so as to minimize adulteration and variances in product strength and quality as well as errors in administration, and failed to package in such a way as to adequately warn prescribers and users of limited efficacy, lack of evidence for unapproved uses, and serious adverse effects;

(d) Failed to conduct adequate pre-clinical and clinical testing to determine the safety of Risperdal and/or Invega, including failure to adequately train clinical investigators as to the risks and benefits of Risperdal and/or Invega and proper methods of monitoring patients;

(e) Failed to perform adequate and proper post-marketing safety surveillance for Risperdal and/or Invega which would have revealed an association between Risperdal and/or Invega and serious and life-threatening adverse effects including but not limited to rapid weight gain, hyperglycemia, diabetes mellitus, diabetic ketoacidosis, hyperosmolar coma, death, pancreatitis, hyperprolactinemia, gynecomastia, tardive dyskinesia, extrapyramidal symptoms, and other serious and life-threatening side effects, all of which existed and were known or, in the exercise of due diligence, should have been known by Janssen; and, to the extent that Janssen learned of such adverse effects, it failed to report them to the FDA, physicians, and patients and/or concealed such information from them;

(f) Illegally promoted off-label uses of Risperdal and/or Invega for which there was little or no scientific evidence of safety and efficacy;

(g) Promoted Risperdal and/or Invega by means of false and misleading claims, failing to include fair balance between risks and benefits, and encouraging off-label uses in advertisements, professional meetings, medical journal articles, advisory meetings, promotional speaking, continuing medical education,

leavebehinds at prescribers' offices, detailing, and by other methods and materials;

(h) Failed to label Risperdal and/or Invega so as to convey knowledge concerning Risperdal and/or Invega' approved uses, risks, and benefits in an accurate and timely manner, and to update labeling as necessary;

(i) Failed to warn the FDA, prescribing physicians, and users, including Plaintiffs, of the true risks of adverse events associated with Risperdal and/or Invega;

(j) Failed to distribute Risperdal and/or Invega properly so as to include adequate warnings and restrictions on unapproved uses;

(k) Failed to conduct sales of Risperdal and/or Invega properly in that Janssen sales representatives made false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Risperdal and/or Invega;

(l) Failed to provide adequate training and education to, and failed to adequately supervise, its sales representatives so as to prevent them from making false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Risperdal and/or Invega; and encouraged such illegal activities by means of sales promotions, contests, and bonuses;

(m) Failed to accompany Risperdal and/or Invega with proper warnings regarding serious adverse side effects associated with the use of Risperdal and/or Invega;

(n) Failed to provide adequate training and instruction to medical care providers for appropriate use of Risperdal and/or Invega;

(o) Failed to warn Plaintiffs, prior to use of Risperdal and/or Invega, either directly or indirectly (through Plaintiffs' prescribing physician), orally or in writing, about the following:

i. The signs and symptoms of known serious adverse events including but not limited to rapid weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, tardive dyskinesia, and potentially fatal side effects;

ii. The need for diagnostic tests to be performed on the patient prior to and during use of Risperdal and/or Invega to discover and ensure against serious or potentially fatal side effects; and

iii. The need for comprehensive, regular medical monitoring to ensure early discovery of serious or potentially fatal side effects;

(p) Failed to warn that the risks associated with the ingestion and/or injection of Risperdal and/or Invega exceeded the risks of other available forms of treatment for Plaintiffs' condition;

(q) Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of Risperdal and/or Invega either together or with various other drugs or use in treatment of Plaintiffs' condition;

(r) Marketed Risperdal and/or Invega despite the fact that the risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

(s) Represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Risperdal and/or Invega from the FDA, prescribing physicians and the consuming public;

(t) Remained silent despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of ingestion and/or injection of Risperdal and/or Invega and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiffs;

(u) Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or with reasonable certainty should have known, that their drug was being prescribed in a fatal or injurious combination or manner; and

(v) Were otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for the rights of Plaintiffs.

193. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega, and the acts and failure to act by the Janssen Defendants, Plaintiffs were caused to develop the aforesaid injuries and damages.

194. The Janssen Defendants' conduct is outrageous because of willful or reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT II
FRAUD

195. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

196. Janssen knowingly and intentionally made false and misleading statements regarding the uses, safety, and efficacy of Risperdal and/or Invega, and/or concealed, suppressed, and omitted important information regarding the uses, safety, and efficacy of Risperdal and/or Invega, in general, and in treating conditions such as those of Plaintiffs, to Plaintiffs' and to Plaintiffs' prescribing physicians.

197. These deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein, including, but not limited to:

(a) Making false and misleading claims regarding the known risks of Risperdal and/or Invega and/or suppressing, failing to disclose and mischaracterizing the known risks of Risperdal and/or Invega, including, but not limited to, rapid weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, diabetic ketoacidosis, tardive dyskinesia, and death;

(b) Making false and misleading written and oral statements that Risperdal and/or Invega are more effective than other antipsychotic drugs and/or omitting material information showing that Risperdal and/or Invega are no more effective than other available antipsychotic drugs;

(c) Misrepresenting or failing to timely and fully disclose the true results of clinical tests and studies related to Risperdal and/or Invega;

(d) Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of ingesting and/or being injected with Risperdal and/or Invega which would disclose the nature and extent of the harmful side effects of Risperdal and/or Invega;

(e) Making false and misleading claims that adequate clinical testing had been done and/or failing to disclose that adequate and/or generally accepted standards for pre-clinical and clinical testing had not been followed;

(f) Making false and misleading claims that adequate, standard, and/or generally accepted methods of post-marketing safety surveillance had been performed and that Risperdal and/or Invega are safe and effective, and/or failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done;

(g) Making false and misleading misrepresentations concerning the safety, efficacy and benefits of Risperdal and/or Invega as detailed in this complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading; and

(h) Insisting on confidentiality agreements in other litigation concerning Risperdal and refusing to produce documents unless Plaintiffs in that litigation agreed, then over-designating nearly every document produced as confidential, despite the absence of any reasonable expectation that such documents were trade secrets or that they required protection to avoid any particular harm to Defendants, which was done for the improper purpose of preventing the public from learning about the true risks of adverse effects associated with Risperdal.

198. The Janssen Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that Risperdal and/or Invega were associated with adverse effects which are injurious or fatal.

199. The Janssen Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding the uses, safety and efficacy of Risperdal and/or Invega, and did so because the prospect of enormous future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including Plaintiffs.

200. The Janssen Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression and concealment of material facts, made with the intent that the FDA, physicians and consumers, including Plaintiffs, would rely upon such

misrepresentation, concealment, suppression or omission, in connection with the marketing, sale and use of Risperdal and/or Invega.

201. The FDA, physicians and Plaintiffs did not know, and could not learn, the truth concerning the uses, risks and benefits of Risperdal and/or Invega due to Janssen's deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding Risperdal and/or Invega. The facts and information misrepresented, concealed, suppressed and omitted by Janssen are material, and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in the prescribing doctors' decision to prescribe Risperdal and/or Invega to Plaintiffs and in Plaintiffs' decision to use Risperdal and/or Invega and/or to give them to their children.

202. Plaintiffs, directly and/or through their prescribing physicians, were induced by Janssen's misrepresentations, omissions, suppression and concealment to agree to use and to have their children use Risperdal and/or Invega.

203. As a direct and proximate result of the aforesaid fraudulent conduct by Janssen, Plaintiffs and/or their children were caused to use Risperdal and/or Invega and suffered the aforesaid injuries and damages.

204. The Janssen Defendants' conduct is outrageous because of willful or reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT III
STRICT PRODUCT LIABILITY
(Failure to Warn)

205. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

206. The Risperdal and/or Invega manufactured and/or distributed and/or supplied by Janssen was defective and unreasonably dangerous due to inadequate post-marketing warnings or instructions because Janssen failed to provide adequate warnings to users or consumers of Risperdal and/or Invega and continued to aggressively promote these dangerous and defective drug products.

207. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega were associated with rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions, the Janssen Defendants recklessly, negligently, and with willful and wanton indifference to the health and safety of consumers including Plaintiffs, failed to provide an adequate warning with regard to hyperglycemia, diabetes mellitus, or related conditions until or after December 2003. Prior to that time the label was defective in that it failed to advise prescribing doctors or the public, including Plaintiffs that Risperdal was associated with hyperglycemia, diabetes, and related conditions; that patients on

Risperdal should undergo fasting blood sugar tests before and during treatment if they have risk factors for diabetes or develop "symptoms" of hyperglycemia; and that treatment should be stopped if symptoms of hyperglycemia or diabetes mellitus appeared. In fact, the December 2003 label is still defective in that it does not contain a black box warning for diabetes; does not clearly state that Risperdal is associated with hyperglycemia, diabetes mellitus, and related conditions; fails to state the true incidence of those conditions in Risperdal patients; and recommends blood glucose testing only for patients with "risk factors" and those who develop "symptoms" of hyperglycemia.

208. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega are associated with rapid weight gain, the label for Risperdal failed, and continues to fail, to include an adequate warning as to the true risks of weight gain associated with Risperdal and/or Invega. Recently, an FDA Pediatric Advisory Panel voted unanimously that the warning in the atypical antipsychotic labeling for weight gain was inadequate.

209. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega are associated with hyperprolactinemia, gynecomastia and galactorrhea, the label for Risperdal and/or Invega failed, and continues to fail, to include an adequate warning as to the true risks of hyperprolactinemia and gynecomastia associated with Risperdal.

210. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega are associated with hyperprolactinemia, gynecomastia and galactorrhea in Janssen clinical trials, that information was deliberately withheld from prescribing physicians and the public until at least October 2006, when it appeared in the label for Risperdal and/or Invega.

211. Even now, the warnings in the labeling for Risperdal and/or Invega are inadequate and fail to include significant information in Jansenn's possession regarding postmarketing adverse event reports of these and related adverse events.

212. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega are associated with tardive dyskinesia and extrapyramidal symptoms, the label for Risperdal and/or Invega failed, and continues to fail, to include an adequate warning as to the true risks of tardive dyskinesia and extrapyramidal symptoms associated with Risperdal and/or Invega.

213. Despite the warnings, if any, in the label for Risperdal and/or Invega, the Janssen defendants intentionally downplayed and minimized any such warnings in promotional materials, CME, presentations at medical meetings, and in visits by sales representatives to doctors' offices so as to cause doctors and patients, including Plaintiffs, to remain unaware of the true nature and extent of serious side effects of Risperdal and/or Invega.

214. As a result of the foregoing, Risperdal and Invega are both defective and unreasonably dangerous drug products.

215. As a direct and proximate result of ingestion or injection with of Risperdal and/or Invega and the aforesaid acts and failure to act by Janssen, Plaintiffs were caused to suffer the aforesaid injuries and damages. Janssen's conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT IV
STRICT PRODUCT LIABILITY

216. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

217. The Risperdal and/or Invega manufactured, distributed, and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

218. Alternatively, the Risperdal and/or Invega manufactured and/or distributed and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other atypical antipsychotic drugs.

219. There existed, at all times material hereto, safer alternative medications.

220. Janssen did not perform adequate testing on Risperdal and/or Invega. Adequate testing would have shown that Risperdal and/or Invega cause serious adverse effects with respect to which full and proper warnings that accurately and fully reflected symptoms, scope and severity should have been made.

221. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega and the aforesaid acts and failure to act by Janssen, Plaintiffs were caused to suffer the aforesaid injuries and damages.

222. Janssen's conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT V
NEGLIGENT MISREPRESENTATION

223. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

224. Prior to Plaintiffs' first dose of Risperdal and/or Invega, and during the period in which Plaintiffs used Risperdal and/or Invega, Defendants misrepresented the degree to which Risperdal and Invega provided a safe and effective treatment.

225. Defendants failed to disclose material facts regarding the safety and efficacy of Risperdal and Invega, including information regarding increased adverse events and harmful side effects.

226. Defendants had a duty to provide Plaintiffs, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the Risperdal and Invega products they marketed, distributed, and sold.

227. Defendants knew or should have known, based on prior experience, adverse events reports, studies and knowledge of the efficacy and safety failure associated with Risperdal and Invega that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of Risperdal and Invega.

228. Defendants made the representations and otherwise failed to disclose materials facts concerning Risperdal and Invega with the intent to induce patients, including Plaintiffs, to act in reliance thereon in using Risperdal and/or Invega during the course of treatment.

229. Plaintiffs justifiably relied on Defendants' representations and non-disclosures in choosing to use Risperdal and/or Invega.

230. As a direct and proximate consequence of Janssen's negligence, willful, wonton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiffs sustained the injuries and damages described herein.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VI
BREACH OF EXPRESS WARRANTY

231. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

232. The Janssen Defendants expressly warranted that Risperdal and/or Invega are safe and effective and that Risperdal and/or Invega were well tolerated in adequate and well-controlled clinical studies.

233. Risperdal and/or Invega do not conform to these express representations because Risperdal and/or Invega are not safe and both cause high levels of serious, life-threatening side effects.

234. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega and the aforesaid acts and failure to act by Janssen, Plaintiffs were caused to develop the aforesaid injuries and damages.

235. The Janssen Defendants' conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VII
BREACH OF IMPLIED WARRANTY

236. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

237. At the time the Janssen Defendants marketed, sold and distributed Risperdal and/or Invega for use by Plaintiffs and the consuming population, Janssen knew of the use for which Risperdal and/or Invega were intended and impliedly warranted Risperdal and/or Invega to be of merchantable quality and safe and fit for such use.

238. Plaintiffs reasonably relied upon the skill and judgment of Janssen as to whether Risperdal and/or Invega were of merchantable quality and safe and fit for their intended use.

239. Contrary to such implied warranty, Risperdal and/or Invega were not of merchantable quality or safe or fit for their intended use, because Risperdal and/or Invega were and are unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.

240. As a direct and proximate result of Plaintiffs' ingestion of Risperdal and/or Invega and the aforesaid acts and failure to act by the Janssen Defendants, Plaintiffs were caused to suffer the aforesaid injuries and damages.

241. The Janssen Defendants' conduct is outrageous because of reckless indifference to the health and safety of the Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VIII
VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT, CHAPTER 407 OF THE REVISED STATUTES OF MISSOURI

242. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

243. All Defendants committed unfair or deceptive acts or practices as follows:

(a) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Risperdal and/or Invega;

(b) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another, of Risperdal and/or Invega;

(c) Representing that Risperdal and/or Invega have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;

(d) Representing that Janssen authors and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;

(e) Representing that Risperdal and/or Invega are of a particular standard, quality or grade;

(f) Disparaging the goods, services or business of other pharmaceutical manufacturers by false or misleading representation of fact;

(g) Failing to comply with the terms of a written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made; and

(h) Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Petition.

244. Defendants' unfair and deceptive acts occurred in connection with the sale or advertisement of Risperdal and/or Invega.

245. Plaintiffs have suffered injuries and damages as a direct and proximate result of Defendants' statements in the advertising and promotional activities to the Plaintiffs' medical providers, as described above.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT IX
CONSPIRACY

246. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

247. On information and belief, Janssen, by and through its officers, directors, servants, employees, and agents conspired and met with medical writers and officers, directors, servants, employees, by videoconference, telephone and email, and in person, to discuss and agree on plans to create, publish, distribute, and present posters, abstracts, medical journal articles, and oral and written presentations at Janssen-sponsored events, at professional meetings, and as part of purported CME.

248. Defendants conspired to recruit and use, and did use, academicians and other influential persons in the medical community as "key opinion leaders" to serve as named authors and presenters, despite the fact that the authors and presenters had little or no personal involvement in research on Risperdal and/or Invega, or in the analysis of data, or in the actual authorship of these materials.

249. These meetings were held for an illegal purpose, *i.e.*, the promotion of off-label uses of Risperdal and/or Invega and the creation of false and misleading promotional materials

designed to create a false impression in the minds of physicians that Risperdal and/or Invega are safe and effective for a variety of uses, labeled and unlabeled, that Risperdal and/or Invega are "broad spectrum antipsychotics," that Risperdal and/or Invega were safe and effective in the treatment of children and adolescents (prior to approval of any use in children and adolescents in the United States), and that Risperdal and/or Invega were safe and effective in the treatment of conditions for which Risperdal and/or Invega have never been approved in the United States, *i.e.*, autism, Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, Post-Traumatic Stress Disorder (PTSD), pervasive development disorders (PDD), and substance abuse.

250. Plaintiffs and other consumers have been damaged as a direct and proximate result of Defendants' concerted actions, as alleged above.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT X
MEDICAL EXPENSES INCURRED BY PARENT

251. Plaintiff(s) incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows.

252. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) necessarily paid and has (have) become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expense of a similar nature in the future

253. Said Plaintiffs incurred expenses for doctors' visits, prescriptions for Risperdal and/or Invega, and examination, testing, and treatment in an effort to cure Plaintiffs of injuries sustained as a result of their use of Risperdal and/or Invega, incurred travel expenses in connection with same, and lost time from work and income, all as a proximate and direct result of the wrongful acts of Defendants, and will continue to do so in the future.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants as follows:

a. For judgment for damages sufficient to compensate for damages in excess of $25,000.00, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiffs as a result of using Risperdal®;

b. For compensatory damages according to proof;

c. Loss of earnings and impaired earning capacity according to proof at the time of trial;

d. Medical expenses, past and future, according to proof at the time of trial;

e. For past and future mental and emotional distress, according to proof;

f. For all applicable statutory remedies provided that assert liability for Defendants' wrongdoings and improper conduct;

g. For a disgorgement of profits;

h. For prejudgment interest, as permitted by law;

i. For reasonable costs, including attorneys' fees, as permitted by law;

j. For punitive damages, as permitted by law; and

k. For all other just and proper relief which may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all claims so triable.

Dated: 02/27/2017

Respectfully submitted,

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